

*Place:* The George Washington University Inn, 824 New Hampshire Ave., NW, Washington, DC 20037.

*Contact Person:* Joseph Kimm, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5178 MSC 7844, Bethesda, MD 20892, (301) 435-1249.

*Name of Committee:* Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Integrative, Functional and Cognitive Neuroscience 5.

*Date:* February 19–20, 2002.

*Time:* 8:30 AM to 10:30 AM.

*Agenda:* To review and evaluate grant applications.

*Place:* Governor's House Hotel, 17th & Rhode Island Avenue, NW, Washington, DC 20036.

*Contact Person:* John Bishop, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5180, MSC 7844, Bethesda, MD 20892, (301) 435-1250.

*Name of Committee:* Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Integrative, Functional and Cognitive Neuroscience 4.

*Date:* February 20–21, 2002.

*Time:* 8:00 AM to 4:00 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* Wyndham Washington Hotel, 1400 M Street NW, Washington, DC 20005–2750.

*Contact Person:* Dan Kenshalo, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, (301) 435-1255.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel.

*Date:* February 20, 2002.

*Time:* 8:00 AM to 10:00 AM.

*Agenda:* To review and evaluate grant applications.

*Place:* Georgetown Holiday Inn, Kaleidoscope Room, 2101 Wisconsin Ave. NW, Washington, DC 20007.

*Contact Person:* Dharam S. Dhindsa, DVM, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5126, MSC 7854, Bethesda, MD 20892, (301) 435-1174, [dhindsad@csr.nih.gov](mailto:dhindsad@csr.nih.gov).

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Molecular, Cellular and Developmental Neurosciences 5.

*Date:* February 20–21, 2002.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Jurys Washington Hotel, Westbury Conference Room, 1500 New Hampshire Avenue, NW., Washington, DC 20036.

*Contact Person:* Syed Husain, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7850, Bethesda, MD 20892, (301) 435-1224.

*Name of Committee:* Infectious Diseases and Microbiology Integrated Review Group, Bacteriology and Mycology Subcommittee 2.

*Date:* February 20–21, 2002.

*Time:* 8:30 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Latham Hotel, 3000 M Street, NW., Washington, DC 20007.

*Contact Person:* Lawrence N. Yager, PHD, Scientific Review Administrator, Center For Scientific Review, National Institutes of Health, 6701 Rockledge Drive MSC 7808, Room 4190, Bethesda, MD 20892, 301-435-0903, [yagerl@csr.nih.gov](mailto:yagerl@csr.nih.gov).

*Name of Committee:* Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Integrative, Functional and Cognitive Neuroscience 1.

*Date:* February 20–21, 2002.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Wyndham Washington Hotel, 1400 M Street NW., Washington, DC 20005–2750.

*Contact Person:* Gamil C. Debbas, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7844, Bethesda, MD 20892, (301) 435-1018.

*Name of Committee:* Biophysical and Chemical Sciences Integrated Review Group, Medicinal Chemistry Study Section.

*Date:* February 20–21, 2002.

*Time:* 8:30 a.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Ronald J. Dubois, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4156, MSC 7806, Bethesda, MD 20892, (301) 435-1722.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel.

*Date:* February 20, 2002.

*Time:* 10 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Georgetown Holiday Inn, kaleidoscope Room, 2101 Wisconsin Ave. NW., Washington, DC 20007.

*Contact Person:* Dharam S. Dhindsa, DVM, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5126, MSC 7854, Bethesda, MD 20892, (301) 435-1174, [dhindsad@csr.nih.gov](mailto:dhindsad@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel

*Date:* February 20, 2002.

*Time:* 11:00 AM to 5:00 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* Governor's House Hotel, 17th & Rhode Island Avenue, NW., Washington, DC 20036.

*Contact Person:* John Bishop, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5180, MSC 7844, Bethesda, MD 20892, (301) 435-1250.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel.

*Date:* February 20, 2002.

*Time:* 2:00 PM to 3:30 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

*Contact Person:* Zakir Bengali, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, MSC 7842, Bethesda, MD 20892, (301) 435-1742.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel.

*Date:* February 20, 2002.

*Time:* 7:00 PM to 10:00 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* La Jolla Coves Suites, 1155 Coast Blvd., La Jolla, CA 92037.

*Contact Person:* Eileen W. Bradley, DSC, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, (301) 435-1179, [bradleye@csr.nih.gov](mailto:bradleye@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel.

*Date:* February 20, 2002.

*Time:* 7:00 PM to 10:00 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* La Jolla Coves Suites, 1155 Coast Blvd., La Jolla, CA 92037.

*Contact Person:* Lee Rosen, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435-1171.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306, 93.333, Clinical Research, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02–2899 Filed 1–30–02; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

**National Institute of Environmental Health Sciences (NIEHS); National Toxicology Program (NTP); Report on the Revised Up-and-Down Procedure: A Test Method for Determining the Acute Oral Toxicity of Chemicals; Notice of Availability and Request for Public Comments**

**SUMMARY:** Notice is hereby given of the availability of the report entitled, "The Revised Up-and-Down Procedure: A

Test Method for Determining the Acute Oral Toxicity of Chemicals," NIH Publication 02-4501. The report contains the final test recommendations on the "Revised Up-and-Down Procedure" (Revised UDP) by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the results of an independent scientific peer review evaluation of the Revised UDP, and the final test guideline for the Revised UDP. The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) is seeking public comment on this report on behalf of the ICCVAM prior to transmittal to US Federal agencies in accordance with Pub. L. 106-545. The report and public comments will be transmitted to appropriate Federal agencies following this public comment period.

#### Availability of the Report

The report is available electronically (PDF and HTML) on the ICCVAM/NICEATM Web site, <http://iccvam.niehs.nih.gov>. A limited number of printed reports are available. To receive a printed copy, please contact NICEATM at PO Box 12233, MD EC-17, Research Triangle Park, NC 27709 (mail), 919-541-2384 (phone), 919-541-0947 (fax), or [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov) (e-mail).

#### Request for Public Comments

NICEATM invites written public comments on the report. Comments should be sent to NICEATM no later than March 25, 2002. Comments submitted via e-mail are preferred; the acceptable file formats are MS Word (Office 98 or older), plain text, or PDF. Comments should be sent to Dr. William S. Stokes, Director, NICEATM, at PO Box 12233, MD EC-17, Research Triangle Park, NC 27709 (mail), 919-541-0947 (fax), or [niceatmcomments@niehs.nih.gov](mailto:niceatmcomments@niehs.nih.gov) (e-mail). Persons submitting written comments should include their contact information (name, affiliation, address, telephone and fax numbers, and e-mail) and sponsoring organization, if any. Public comments received by the above deadline will be posted on the ICCVAM/NICEATM Web site, <http://iccvam.niehs.nih.gov>, and forwarded to the appropriate Federal agencies with the report.

#### Background

The Organisation for Economic Cooperation and Development (OECD) Test Guidelines Program (TG 425; OECD 1998) adopted the UDP in 1998. The U.S. Environmental Protection Agency (EPA) subsequently determined it was

necessary to revise the UDP to: (1) Conform to a newly harmonized global hazard classification scheme for acute toxicity (OECD, 2001) and (2) ensure that regulatory and testing needs would be met with the Revised UDP prior to OECD's proposed deletion of the conventional acute oral toxicity test (OECD, 1987). In August 1999, the EPA asked ICCVAM to evaluate the validation status of the Revised UDP as a substitute for the existing conventional LD50 test (U.S. EPA 870.1100, 1998; OECD Test Guideline (TG) 401, 1987).

The Revised UDP test method submitted to ICCVAM for evaluation included three components:

- A Primary Test for estimating the median lethal dose using sequential testing.
- A Limit Test for evaluating substances anticipated to have minimal or no toxicity.
- A Supplemental Test to determine the slope and confidence interval (CI) for the dose-response curve.

An initial **Federal Register** notice (Vol. 65, No. 34, pp. 8385-8386, February 18, 2000) requested data and the nomination of expert scientists to participate in the independent scientific peer review evaluation of the Revised UDP. A second **Federal Register** notice (Vol. 65, No. 106, pp. 35109-35110, June 1, 2000) announced the peer review panel meeting, availability of a background review document on the Revised UDP, and requested public comments.

The first meeting of the Panel to evaluate the Revised UDP was held on July 25, 2000. The public meeting was organized by the ICCVAM and NICEATM and was sponsored by the NIEHS, NTP, and EPA. The Panel evaluated the extent to which the Revised UDP addresses established validation and acceptance criteria (ICCVAM, 1997) and develops conclusions regarding the usefulness and limitations of the Revised UDP.

The Panel agreed that the Primary and Limit tests would perform as good or better than the respective existing conventional LD50 and limit tests. They also agreed that the revised test methods would reduce animal use compared to the current test methods. The Panel provided other recommendations for revision of the Revised UDP test guideline and did not recommend the UDP Supplemental Test.

Based on the Panel's July 25, 2000 conclusions and recommendations, the EPA UDP Technical Task Force modified the UDP Primary and Limit Tests and removed the UDP Supplemental Test. A computational

procedure was added to calculate the confidence interval (CI) for the estimated LD50. The EPA also developed a software program that would calculate subsequent test doses, determine when to stop the test, estimate the LD50, and calculate a CI for the LD50. The publicly available software was developed to mitigate complexity for the user and to facilitate correct performance of the Revised UDP.

A **Federal Register** notice (Vol. 66, No. 121, pp. 33550-33552, June 22, 2001) requested public comment and announced availability of the revised draft test guideline for the Revised UDP, the procedure for calculating the confidence interval for the estimated LD50, and the software program. A subsequent **Federal Register** notice (Vol. 66, No. 133, pp. 36294-36295, July 11, 2001) announced a second public meeting of the UDP Panel.

The second meeting of the UDP Panel was held by teleconference on August 21, 2001. The Panel reviewed and endorsed modifications to the Revised UDP, the CI procedure, and the software program. The Panel recommended additional clarifications to the Revised UDP. Written reports of the Panel meetings are included in the final report.

Following the August 21st meeting, the EPA UDP Technical Task Force revised the UDP Guideline in response to the Panel's recommendations. A discussion of software program limitations and information about using *in vitro* cytotoxicity data to estimate starting doses for *in vivo* studies were added. An ICCVAM Acute Toxicity Working Group and the ICCVAM reviewed and endorsed the final Revised UDP Test Guideline, and developed and adopted ICCVAM test method recommendations for the Revised UDP. In accordance with P.L. 106-545, the ICCVAM test recommendations will be forwarded to appropriate Federal agencies for acceptance consideration.

The final report comprises two volumes. The first volume (143 pages) includes the final ICCVAM test method recommendations on the Revised UDP procedure, the final Revised UDP Test Guideline, and the two peer review panel meeting reports. Volume 2 (291 pages) contains an updated background review document and other information considered by the Panel for the July 2000 meeting. Following receipt of public comments, the report will be forwarded to Federal agencies in accordance with Pub. L. 106-545.

## Additional Information About ICCVAM and NICEATM

The NICEATM and ICCVAM were established to facilitate development, validation, and regulatory acceptance of improved toxicological methods that predict human health risks while reducing, refining, and/or replacing animal tests and to promote communication with stakeholders. The NICEATM coordinates activities for the ICCVAM and is located at the NIEHS, Research Triangle Park, NC. ICCVAM, with 15 participating Federal agencies, originally established in 1997, was formally authorized and designated as a permanent interagency coordinating committee by the ICCVAM Authorization Act of 2000 (Pub. L. 106-545). ICCVAM's duties include the technical evaluation of new and alternative testing methods, the development of test recommendations based on those technical evaluations, and the forwarding of its test recommendations to Federal agencies for their consideration. The ICCVAM also coordinates interagency issues on toxicological test method development, validation, regulatory acceptance, and national and international harmonization. Additional information about ICCVAM and NICEATM can be found on the ICCVAM/NICEATM Web site at <http://iccvam.niehs.nih.gov>.

## References

Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). 1997. Validation and regulatory acceptance of toxicological test methods: A report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods. NIH publication no: 97-3981. National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina. Available: <http://iccvam.niehs.nih.gov/docs/guidelines/validate.pdf> (cited October 1, 2001).

National Institute of Environmental Health Sciences (NIEHS). 2000a. National Toxicology Program: Request for Data and Nomination of Expert Scientists to Participate in the Independent Peer Review Evaluation of the Revised Up-and-Down Procedure for Assessing Acute Oral Toxicity. Evaluation of the Up-and-Down Procedure. 65 FR 8385. February 18, 2000.

NIEHS. 2000b. National Toxicology Program: Notice of Peer Review Meeting on the Revised Up-and-Down Procedure (UDP) as an Alternative Test Method for Assessing Acute Oral Toxicity. Request

for Comments. 65 FR 35109. June 1, 2000.

NIEHS. 2001a. National Toxicology Program: The Revised Draft Up-and-Down Procedure for Assessing Acute Oral Toxicity. Notice of Availability and Request for Public Comments. 66 FR 33550. June 22, 2001.

NIEHS. 2001b. National Toxicology Program: Notice of Peer Review Meeting on the Revised Up-and-Down Procedure (UDP) as an Alternative Test Method for Assessing Acute Oral Toxicity. 66 FR 36294. July 11, 2001.

OECD. 1998. OECD Guideline for the Testing of Chemicals, Revised Test Guideline 425, Acute Oral Toxicity, Up-and-Down Procedure. OECD, Paris. Available: <http://www.oecd.org/ehs/test/health.htm> (cited October 1, 2001).

OECD. 2001. Harmonized Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures. ENV/JM/MONO(2001)6. OECD, Paris. Available: <http://www.oecd.org/ehs/class/HCL6.htm> (cited December 13, 2001).

OECD. 1987. OECD Guideline for the Testing of Chemicals, Test Guideline 401, Acute Oral Toxicity. OECD, Paris. Available: <http://www.oecd.org/ehs/test/health.htm> (cited October 1, 2001).

U.S. EPA. 1998. Health Effects Test Guidelines, OPPTS 870.1100, Acute Oral Toxicity. Washington, DC, U.S. Environmental Protection Agency. Available: [http://www.epa.gov/docs/OPPTS\\_Harmonized/870\\_Health\\_Effects\\_Test\\_Guidelines/Series/](http://www.epa.gov/docs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/) (cited October 1, 2001).

Dated: January 11, 2002.

**Samuel H. Wilson,**

*Deputy Director, National Institute of Environmental Health Sciences.*

[FR Doc. 02-2905 Filed 2-6-02; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

### National Toxicology Program (NTP); The NTP Annual Plan for Fiscal Year 2001; Notice of Availability and Request for Public Comments

**SUMMARY:** The *NTP Annual Plan for Fiscal Year 2001* outlines the NTP research program for studying the toxicity of physical and chemical agents and for developing methods for toxicological evaluations. The Report also provides information about efforts to develop and validate alternative and improved methods and identifies NTP resource allocations.

## Background

The NTP was established within the Public Health Service of the Department of Health and Human Services (DHHS) in November 1978. The NTP is an interagency program whose mission is to evaluate agents of public health concern by developing and applying the tools of modern toxicology and molecular biology. In carrying out its mission, the NTP has several goals to:

- Broaden the spectrum of toxicological information obtained on selected chemicals;
- Develop and validate more sensitive and specific test methods;
- Develop improved strategies for generating scientific data that strengthen the scientific foundation for risk assessments; and
- Communicate NTP plans and results to government agencies, the medical and scientific communities, and the public.

A balanced program was created that uses chronic exposure studies, short-term exposure studies, the collection and application of mechanistic information, model development, alternative methods, and human studies. Scientific activities are divided into several major program areas: Carcinogenesis, risk assessment research, alternative test systems, and toxicology. Toxicology covers activities in immunotoxicology, neurobehavioral toxicology, reproductive and developmental toxicology, respiratory toxicology and phototoxicology. Program and project leaders along with contact information are provided in the plan.

The NTP is an interagency program headquartered at the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health. The NIEHS along with the National Center for Toxicological Research of the Food and Drug Administration and the National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention are NTP core agencies. The Director of the NIEHS is also the NTP Director.

The NTP receives advice from two primary external advisory groups. The NTP Executive Committee provides primary program oversight and links DHHS health research institutes and centers with Federal health regulatory agencies. This effort helps to ensure that the NTP's basic and applied toxicology research and development activities are responsive to regulatory and public health needs.

The NTP Board of Scientific Counselors provides scientific oversight